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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/657,472 | 09/08/2003 | Tracee Eidenschink | S63.2H-11273-US01 | 2675 |
| 23552 | 7590 | 10/12/2006 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | GILBERT, ANDREW M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/657,472 | Applicant(s) EIDENSCHINK ET AL. | |
| | Examiner Andrew M. Gilbert | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6-11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/3/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/19/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2006 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/19/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings are objected to because Figure 5 fails to show reference number 25. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Art Unit: 3767

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The use of the trademark "TECOPHILIC" has been noted in this application. **It should be capitalized wherever it appears** and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-11 recite the limitation "any combination thereof". The recitation fails to particularly point out and distinctly claim the agents or cellular material that the applicant regards as the invention. The Applicant has recited a

Art Unit: 3767

seemly infinite amount of agents or cellular material by the inclusion of "any combination thereof". The Examiner suggests removing the limitation "any combination thereof".

7. Claim 11 additionally recites the limitation "etc." on Ln 13. The Examiner does not know the distinct meaning or metes and bounds of the use of "etc."; thus, the claim is rendered indefinite. The Examiner recommends removing the limitation "etc." from the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2, 3, 6, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (6165195). Wilson et al discloses a catheter assembly comprising: a catheter, the catheter comprising a catheter shaft (50), the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough; a rotatable sheath (54), the rotatable sheath extending around an exterior of at least a portion of the catheter shaft and rotatable about the catheter shaft at a position radially outward from the catheter shaft (54, Figs 12G-12I, 16B-D; wherein the Examiner notes that the sheath does extend around at least a portion of the catheter shaft, ie the when inflated the sheath, ie the balloon, extends around the portion of the catheter shaft housing the guidewire lumen; furthermore, the sheath is rotatable about the catheter shaft at a position radially outward, ie when the balloon is inflated, the sheath rotates about when

Art Unit: 3767

the entire catheter shaft is rotated manually, as it reads the limitation does not require the sheath to rotate *separately or independently* from the catheter shaft and the Examiner recommends including those claims limitations to the claims), the rotatable sheath having a length substantially less than that of the catheter shaft (Figs 12G-12I, 16B-D); a secondary guide wire housing (55a, 55b), the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough (56b), at least a first distal portion of the guide wire housing in contact with at least a first proximal portion of the rotatable sheath (Figs 12G-12I, 16B-D); and a stent (20), the stent being expandable from a reduced stent state to an expanded stent state, and defining a flow path between a proximal end opening and a distal end opening, the stent being at least partially constructed from a plurality of interconnected stent members that define a plurality of cell openings therebetween (Figs 12G-12I, 16B-D), each of the cell openings being in fluid communication with the flow path, in the reduced stent state the stent is positioned radially outward from and extends around an exterior of at least a portion of the rotatable sheath and at least a portion of the secondary guide wire housing (Figs 12G-12I, 16B-D), a distal end portion of the secondary guide wire housing exiting the flow path of the stent through one of the plurality of cell openings (Figs 12G-12I, 16B-D); wherein the stent is selected from at least one member of the group consisting of: a self-expanding stent, a balloon-expandable stent, a hybrid expandable stent and any combination thereof (col 3, Ins 40-43); wherein at least a portion of the stent is coated with at least one therapeutic agent (col 13, Ins 10-15).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al in view of Dayton (5449382). Wilson et al discloses the invention substantially as claimed except for expressly disclosing the one therapeutic agent is from the group listed in claims 7-10. Dayton teaches that it is known to have stents having therapeutic agents (Background and Summary) for the purpose of treating a vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stent as taught by Wilson et al with the therapeutic agent as taught by Dayton for the purpose of treating a vessel.

Double Patenting

12. Claims 2, 3, 6, 13, 14 of this application conflict with claims 1-20, 24-25, 50-46 of Application No. 10/375689.

13. Claims 2-3, 6-11, 13-14 of this application conflict with claims 1-10, 14-31, 33-42 of Application No. 10/747546.

14. Claims 2-3, 6-11, 13-14 of this application conflict with claims 1, 8-11, 13-14, 20-21, 23-28, 46, 48-50 of Application No. 10/863724.

15. Claims 2-3, 6-11, 13-14 of this application conflict with claims 1-46 of Application No. 10/757646.

Art Unit: 3767

16. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 2-3, 6-11, 13-14 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 14-31, 33-42 of copending Application No. 10/747546. Although the conflicting claims are not identical, they are not patentably distinct from each other because limitations in

independent form in the present application are merely included in dependent claims in the '546 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Borghi et al (6056775).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. CHAMBERS
SUPERVISORY PATENT EXAMINER

